EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL NO. 2187

THIS DOCUMENT RELATES TO:

ALL WAVE 9 CASES

DEFENDANT C. R. BARD, INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE OR LIMIT CERTAIN OPINIONS AND TESTIMONY OF BRUCE A. ROSENZWEIG, M.D.

GREENBERG TRAURIG, LLP
Terminus 200
3333 Piedmont Road, N.E., 25th Floor
Atlanta, Georgia 30305
(678) 553-2100

REED SMITH LLP
355 South Grand Avenue, Suite 2900
Los Angeles, California 90071-1514
(213) 457-8000

Attorneys for Defendant C. R. Bard, Inc.

TABLE OF AUTHORITIES

Federal Cases

Rules

Pursuant to Federal Rules of Evidence 702, 403, and 104, Defendant C. R. Bard, Inc. ("Bard") hereby submits this Memorandum of Law in Support of its Motion to Exclude or Limit Certain Opinions and Testimony of Bruce A. Rosenzweig, M.D. (the "Motion"). In support of its Motion, Bard respectfully shows the Court as follows:

INTRODUCTION

Dr. Rosenzweig is a practicing urogynecologist and assistant professor of obstetrics and gynecology. *See* Rule 26 Expert Report of Bruce A. Rosenzweig, M.D. ("Report") at 1-2.[1] This Court has had frequent occasion to consider and rule on the appropriate scope and limits of Dr. Rosenzweig's expert testimony, as he has been previously disclosed as an expert witness for plaintiffs, and called to testify at deposition and/or trial in multiple cases arising under the various MDLs assigned to this Court concerning surgical mesh products used to treat female stress urinary incontinence and pelvic organ prolapse. Specifically, on numerous previous occasions, this Court has ruled on motions to limit or exclude Dr. Rosenzweig's testimony, granting those motions in part and denying them in part in the following opinions and orders:

- Memorandum Opinion and Order (*Daubert* Motions) [Dkt. No. 195] in *Lewis, et al. v. Ethicon, Inc., et al.*, No. 2:12-cv-4301 (Jan. 15, 2014) ("*Lewis* Opinion");
- Memorandum Opinion and Order (*Daubert* Motions) [Dkt. No. 271] in *Huskey, et al. v. Ethicon, Inc., et al.*, No. 2:12-cv-05201 (July 8, 2014) ("*Huskey* Opinion");
- Memorandum Opinion and Order (*Daubert* Motion) [Dkt. No. 139] in *Edwards, et al. v. Ethicon, Inc., et al.*, No. 2:12-cv-09972 (July 8, 2014) ("*Edwards* Opinion");
- Memorandum Opinion and Order (*Daubert* Motion) [Dkt. No. 444] in *Tyree, et al. v. Boston Scientific Corp.*, No. 2:12-cv-08633 (October 17, 2014) ("*Tyree* Opinion");[2]

[1] A true and correct copy of Dr. Rosenzweig's Expert Report, dated October 9, 2014, is annexed to the accompanying Motion as **Exhibit B**.

[2] True and correct copies of the *Lewis*, *Huskey*, *Edwards*, and *Tyree* Opinions are annexed to the accompanying Motion as **Exhibits C through F**.

- Memorandum Opinion and Order (*Daubert* Motions) in *See In re C. R. Bard, Inc., Pelvic Repair Sys. Products Liab. Litig.*, MDL No. 2187, 2018 WL 514753, at *1 (S.D.W. Va. Jan. 23, 2018) ("Bard Wave 4 and 5 Order");

- Memorandum Opinion and Order (*Daubert* Motions) in *In re Boston Sci. Corp. Pelvic Repair Sys. Products Liab. Litig.*, MDL No. 2326, 2018 WL 2426159 (S.D.W. Va. May 29, 2018) ("BCS Order").

The Court's rulings offer clear and succinct guidance regarding the permissible—and impermissible—subjects of Dr. Rosenzweig's testimony. The Court has excluded, in relevant part: (i) testimony regarding defendants' knowledge, state of mind, and corporate conduct (*Lewis* Opinion at 8-10, 34-35; *Huskey* Opinion at 5-6; *Edwards* Opinion at 5-6; Bard Wave 4 and 5 Order at 2; BCS Order at 2); (ii) testimony consisting of reading or giving a narrative description of corporate documents, other than for purposes of providing general background information related to stress urinary incontinence (*Lewis* Opinion at 9, 35-36; *Huskey* Opinion at 10-12; *Edwards* Opinion at 17-18; Bard Wave 4 and 5 Order at 2); (iii) testimony giving legal opinions or drawing legal conclusions from the facts (*Lewis* Opinion at 35; *Huskey* Opinion at 6; *Edwards* Opinion at 6; Bard Wave 4 and 5 Order at 2); (iv) testimony opining on the purported insufficiency of defendants' testing (*Huskey* Opinion at 10; *Edwards* Opinion at 17; BCS Order at 2); (v) testimony opining on the defendant's alleged failure to provide adequate training (*Huskey* Opinion at 18; *Edwards* Opinion at 11-12); (vi) testimony and opinions on the testing of mesh products, including his opinion whether further and more extensive testing of mesh products should have occurred (BCS Order at 2); and (vii) testimony and opinions that there is an association between cancer and polypropylene mesh (BCS Order at 3).

Disregarding the Court's unambiguous direction, the reports and testimony offered by Dr. Rosenzweig in these proceedings introduce precisely the same offending categories of

opinions and testimony this Court has repeatedly excluded. Dr. Rosenzweig's Report and his deposition testimony are replete with previously excluded opinions.

First, he repeatedly presents opinions delving into Bard's knowledge, state of mind, and corporate conduct, often inserting these opinions under an unrelated heading to give them a façade of admissibility.

Second, he supports these opinions with narrative recitations of Bard's corporate documents.

Third, he offers various legal conclusions drawn from the putative facts, including the repeated opinion that Bard "failed to act as a reasonable and prudent medical device manufacturer" by manufacturing and selling its products.

Fourth, he offers opinions he is not qualified to give, and which have no reliable basis, regarding the alleged insufficiency of Bard's testing of its products and patient brochures.

For these reasons, and as supported by this Court's prior rulings, Bard requests that each of the foregoing opinions be excluded.[3]

LEGAL STANDARD

The admissibility of expert opinion testimony is governed by the Federal Rules of Evidence. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993). In accordance with those rules,[4] courts must serve as gatekeepers to the admission of scientific testimony. *See id.* at

[3] Bard reserves the right to move to exclude or limit this expert witness's opinions on grounds other than those set forth in herein if those grounds become available subsequent to the filing of this Motion by virtue of the Court's rulings, any additional discovery that may take place in these cases, or supplementation of this expert witness's disclosure or report.

[4] In a federal court sitting in diversity jurisdiction, the admissibility of expert testimony is a question of and controlled by federal law. *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005); *Grant Thornton, LLP. v. F.D.I.C.*, 297 F. Supp. 2d 880, 882 (S.D.W. Va. 2004). Moreover, in multidistrict litigation, "the court must apply the law of the Fourth Circuit when analyzing questions of federal law." *In re Stucco Litig.*, 364 F. Supp. 2d 539, 540 (E.D.N.C. 2005); *see also Adams v. Boston Sci. Corp.*, 177 F. Supp. 3d 959, 962 (S.D.W. Va. 2016) (Goodwin, J.).

589; *Belville v. Ford Motor Co.*, 919 F.3d 224, 232-33 (4th Cir. 2019). This gatekeeping function applies not only to "scientific" testimony, but also to testimony based on "technical" and "other specialized" knowledge. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999). As such, an expert witness must satisfy three prerequisites before his or her opinion is admissible. *See Daubert*, 509 U.S. at 589-90; *Nease v. Ford Motor Co.*, 848 F.3d 219, 228-29 (4th Cir. 2017) (describing Fourth Circuit's application of *Daubert*), *cert. denied*, 137 S. Ct. 2250 (2017).

First, the expert witness must be adequately qualified by virtue of his or her specialized "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Additionally, the expert's qualifications must be sufficiently related to the particular subjects at issue in the case. *See RG Steel Sparrows Point, LLC v. Kinder Morgan Bulk Terminals, Inc.*, 609 F. App'x 731, 738 (4th Cir. 2015) ("[W]hether a witness is qualified to testify is context-driven and 'can only be determined by the nature of the opinion he offers.'" (quoting *Gladhill v. Gen. Motors Corp.*, 743 F.2d 1049, 1052 (4th Cir. 1984))); *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 392 (D. Md. 2001) (collecting cases regarding the requirement that an expert be qualified to testify regarding the specific issue before the court; "an expert . . . is not necessarily qualified to testify as an expert on any issue within [a] vast field" but "must possess 'some special skill, knowledge or experience' concerning the particular issue before the court" (citation omitted)).

Second, the expert's opinion must be relevant such that it assists "the trier of fact to understand the evidence or to determine a fact in issue." *See* Fed. R. Evid. 702(a). "Expert testimony which does not relate to any issue in the case is not relevant and ergo not helpful." *Daubert*, 509 U.S. at 591; *accord Nease*, 848 F.3d at 229 ("Relevant evidence, of course, is evidence that helps 'the trier of fact to understand the evidence or to determine a fact in issue.'"

(citing *Daubert*, 509 U.S. at 591)). Mere relatedness does not necessarily establish relevancy; *Daubert* further explains:

> The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Huskey v. Ethicon, Inc., 29 F. Supp. 3d 691, 702 (S.D.W. Va. 2014) (Goodwin, J.) (quoting *Daubert*, 509 U.S. at 591-92). Subjects within the understanding of an average juror will not assist the trier of fact and must be excluded. *See, e.g.*, *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 608 (S.D.W. Va. 2013) (Goodwin, J.) (excluding expert testimony as unhelpful because the issue of sexual intimacy "scripts" (or expectations) was understandable to the average juror, even if they did not fully understand the issue in psychological terms); *United States v. Lespier*, 725 F.3d 437, 449 (4th Cir. 2013) ("The helpfulness requirement of Rule 702 . . . prohibits the use of expert testimony related to matters which are 'obviously . . . within the common knowledge of jurors.'" (citation omitted)).

Third, the scientific or technical opinion must be reliable. *See Daubert*, 509 U.S. at 591-92. Expert witnesses must "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co.,* 526 U.S. at 152. To be deemed reliable, an expert opinion must be "based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods." *Nease*, 848 F.3d at 229. Although the *Daubert* court identified several factors that may bear on a court's determination of the reliability of an expert's

testimony,[5] these factors are neither definitive nor exhaustive. *See Kumho Tire Co.*, 526 U.S. at 150; *see also United States v. Crisp*, 324 F.3d 261, 272 (4th Cir. 2003); *In re Lipitor (Atovastatin Calcium) Mktg., Sales Practice & Prods. Liab. Litig. (No II)*, 892 F.3d 624, 637 (4th Cir. 2018). "Expert evidence based on assumptions not supported by the record should be excluded." *Tyger Constr. Co. v. Pensacola Constr. Co.*, 29 F.3d 137, 144 (4th Cir. 1994); *accord Harrison v. United States*, No. 2:07-cv-00696, 2009 WL 36545, at *7 (S.D.W. Va. Jan. 6, 2009).

The proponent of opinion testimony bears the burden of establishing its admissibility. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). Moreover, even if expert opinion testimony is logically relevant, it remains subject to the relevancy requirements of Federal Rule of Evidence 403. *See Trevino v. Boston Sci. Corp.,* No. 2:13-CV-01617, 2016 WL 2939521, at *18 (S.D.W. Va. May 19, 2016) (Goodwin, J.) ("*Daubert* advises courts to keep in mind the other rules of evidence when evaluating expert testimony" and thus excluding expert testimony under Rule 403). Thus, expert testimony must be excluded where its probative value is substantially outweighed by the danger of unfair prejudice. Accordingly, courts exclude "conclusory, speculative, and unsupported" opinions because of its "potential to 'be both powerful and quite misleading,' particularly as to technical or scientific matters." *Casey v. Geek Squad Subsidiary Best Buy Stores, L.P.*, 823 F. Supp. 2d 334, 347-48 (D. Md. 2011) (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). Where, as here, the proponent fails to establish all prerequisites, exclusion of expert testimony is within the court's sound discretion. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997); *Cooper*, 259 F.3d at 200.

[5] Those factors include whether: (1) a theory or technique can be or has been tested; (2) a theory or technique has been subjected to peer review and publication; (3) a technique has a high known or potential rate of error; (4) there are standards controlling a theory or technique's operation; and (5) the theory or technique enjoys general acceptance within a relevant scientific community. *Tunnell v. Ford Motor Co.*, 330 F. Supp. 2d 707, 715 (W.D. Va. 2004) (citing *Daubert*, 509 U.S. at 592-94).

ARGUMENT

I. DR. ROSENZWEIG CANNOT OFFER OPINIONS CONCERNING BARD'S KNOWLEDGE, STATE OF MIND, OR CORPORATE CONDUCT.

This Court has ruled on numerous occasions that Dr. Rosenzweig cannot present his opinions regarding Bard's knowledge, state of mind, or corporate conduct, because such testimony is not helpful to the jury. In the *Lewis* Opinion, the Court explained that a defendant's "knowledge, state of mind, or other matters relating to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." (*Lewis* Opinion at 9-10 (*citing In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 200); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009)). The Court therefore excluded Dr. Rosenzweig's testimony concerning corporate knowledge and state of mind. (*Id*. at 34-35). In the *Huskey*, *Edwards*, and *Tyree* Opinions, the Court reiterated that it "will not permit the parties to use experts to usurp the jury's fact-finding function to determine [defendant's] state of mind or whether [defendant] acted reasonably," emphasizing again that a defendant's "knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." (*Huskey* Opinion at 5-6; *Edwards* Opinion at 5-6; *Tyree* Opinion at 7-8). Similarly, in the Bard Wave 4-5 Order and BCS Order, this Court excluded such evidence. (Bard Wave 4-5 Order at 2; BCS Order at 2).

Notwithstanding this Court's prior rulings, Dr. Rosenzweig's Report and testimony are filled with opinions regarding Bard's purported knowledge, state of mind, and alleged corporate conduct. These opinions are placed under unrelated headings in a transparent effort to introduce them under the guise of other opinions. Hence, under the Report's opinion heading discussing whether Bard's Align mesh is "suitable for its intended application as a permanent prosthetic

implant for stress urinary incontinence," Dr. Rosenzweig launches into numerous long tangents expressing opinions about what Bard "knew" or "should have" known. He states, for example, that Bard "knew about" the alleged unsuitability of its polypropylene resin for human medical device applications and "concealed its use" from the supplier. (Report § III.A.1 at 14).[6] He reaffirmed this opinion at his deposition. (Deposition of Dr. Bruce A. Rosenzweig Vol. I ("Rosenzweig Dep. I") at 180:20-182:4).[7]

Later, Dr. Rosenzweig opines that Bard "should have been aware" of a specific paper concerning degradation of hernia mesh made of polypropylene. (Report § III.A.2 at 19). He also states that Bard had "intimate knowledge" of an article displaying high magnification photos of polypropylene fibers from explanted meshes. (*Id.* § III.A.2 at 21). Dr. Rosenzweig then adds as a rhetorical flourish a "question" challenging Bard's motives and conduct: "This raises the question, if Bard believes the mesh used in its Align products does not degrade in the human body why were top engineers and executives in the company evaluating and interested in mesh that would be allegedly be [sic] resistant to degradation just months after the Clave article was circulated at Bard?" (*Id.* § III.A.2 at 22). In a similar vein, Dr. Rosenzweig later opines that "[d]espite [Bard's] knowledge about the problems related to heavy weight, small pore mesh like the Align mesh and the problems it causes in pelvic tissues and patients, Bard has done nothing to change the mesh and continues to promote and sell the product with the same, heavy weight small pore mesh." (*Id.* § III.A.6 at 40).

[6] Because the Report does not contain numbered pages, references to the Report include both section numbers and page numbers.

[7] True and correct copies of Volumes I through V of the transcripts of Dr. Rosenzweig's deposition, taken October 29-31, 2014, November 29, 2014, and December 18, 2014, are annexed to the accompanying Motion as **Exhibits G through K**.

Dr. Rosenzweig's Report and testimony contain numerous similar opinions regarding knowledge, state of mind, and corporate conduct, with various assertions of what Bard "knew or should have known," "acknowledged," "recognized," "admitted," or "was or should have been aware" of. (*See, e.g.*, Report § III.A.2 at 25, § III.A.4 at 29, § III.A.4 at 32, § III.A.5 at 36-37, § III.A.6 at 38, § III.A.7 at 41, § III.B at 45-48, § III.C.1 at 52-56, § III.D at 59, § III.E at 61; Rosenzweig Dep. I at 232:25-233:7).

None of these "opinions," of course, have anything to do with the underlying question of whether Bard's Align mesh is suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence, or any of the Report's other opinion headings. They are inserted into Dr. Rosenzweig's Report for the sole purpose of questioning Bard's knowledge, state of mind, and corporate conduct, all of which this Court has previously and properly ruled to be inadmissible. All these opinions are improper and should be excluded.

II. DR. ROSENZWEIG CANNOT GIVE NARRATIVE DESCRIPTIONS OF BARD DOCUMENTS.

Together with its exclusion of opinions regarding knowledge, state of mind, and corporate conduct, the Court has also excluded opinions consisting of nothing more than narrative descriptions of the defendants' corporate documents, which are typically the basis for Dr. Rosenzweig's knowledge and state of mind opinions. Bard Wave 4-5 Order at 3. The Court has repeatedly noted that an expert may testify regarding his review of internal corporate documents "solely for the purpose of explaining the basis for his or her opinions," assuming the opinions are otherwise admissible. (*Lewis* Opinion at 9; *Huskey* Opinion at 5-6; *Edwards* Opinion at 5). By contrast, "it is not helpful to the jury to have Dr. Rosenzweig read a document" that "the jury is capable of reading" for itself. (*Huskey* Opinion at 11; *Edwards* Opinion at 17-18). Likewise, an opinion consisting of "a narrative review of corporate documents" is "not

helpful to the jury[.]" (*Huskey* Opinion at 11-12; *Edwards* Opinion at 18). Accordingly, the *Huskey* and *Edwards* opinions excluded "opinions" from Dr. Rosenzweig that either consisted of merely reviewing the defendant's "deposition testimony and internal documents" or were "simply a narrative review of corporate documents." (*Huskey* Opinion at 10-12; *Edwards* Opinion at 17-18).

Once more ignoring this Court's prior rulings, Dr. Rosenzweig again engages in long narrative descriptions of company documents, primarily in support of his inadmissible opinions regarding Bard's alleged knowledge, state of mind, and corporate conduct. To support his opinion that Bard "knew about" and "concealed" the alleged unsuitability of its polypropylene mesh for human medical device implant applications, for example, Dr. Rosenzweig quotes at length from various email chains between Bard employees in 2004 and 2007, and then asks rhetorically why the polypropylene resin manufacturers "would not want this material to be used for permanent human placement." (Report § III.A.1 at 14-16). At deposition, he admitted that he did not "know what these individuals were thinking when they wrote these emails," but was instead letting "the e-mails speak for themselves"—the very definition of improper narrative testimony. (Rosenzweig Dep. I at 180:14-19).

Similarly, to support his opinion that Bard "should have been aware" of a paper regarding degradation of hernia mesh, Dr. Rosenzweig narrates from various company documents in which employees of Covidien (not Bard) expressed respect for the author of that paper. (Report § III.A.2 at 19-20). And in support of his opinion that Bard had "intimate knowledge" of another article, Dr. Rosenzweig undertakes a four-page narration of a series of internal communications among Bard employees regarding the article. (*Id.* § III.A.2 at 20-24).

Indeed, the entire second opinion in Dr. Rosenzweig's Report—captioned "Bard's Align mesh is not suitable for its intended application as a permanent prosthetic implant for SUI in the human body due to the lack of adequate studies supporting its safety and efficacy including Bard's lack of consideration in implanting its products through the obturator space"—consists entirely of narration from Bard internal documents. (Report § III.B at 43-48). Dr. Rosenzweig begins with a generic assertion that a "reasonable and prudent medical device manufacturer should have adequate safety data to support its products before urging surgeons to use them permanently on patients," and then proceeds with a five-page narration of select Bard corporate documents in an attempt to show that Bard "did not adequately understand the importance of clinical data" and proceeded to launch the Align product without adequate data. (*Id.*; *see also* Rosenzweig Dep. I at 295:17-24). Dr. Rosenzweig offers no expertise giving him an advantage over the jury in the fact-finding task of reading and interpreting these corporate documents, and his "opinions" are narrative and editorial, not scientific.

Many similar narrative descriptions of Bard documents and other corporate documents are found throughout Dr. Rosenzweig's Report and testimony, and are offered not as general background on stress urinary incontinence or as scientific evidence to substantiate Dr. Rosenzweig's opinions, but rather as evidence of what Bard "knew or should have known," "acknowledged," "recognized," "admitted," or "was or should have been aware" of. (*See, e.g.,* Report § III.A.2 at 25, § III.A.4 at 29-33, § III.A.5 at 35-37, § III.A.6 at 38-40, § III.A.7 at 41, § III.C.1 at 49, § III.C.1 at 55-56; Rosenzweig Dep. I at 25:6-19, 162:5-163:25 181:10-182:4, 183:25-184:3, 232:25-235:21). This Court has properly excluded such narrative testimony in the past, and should continue to do so in these proceedings.

III. DR. ROSENZWEIG CANNOT GIVE LEGAL OPINIONS.

The Court has "diligently applied" the rule that "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *Sanchez v. Boston Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *4 (S.D.W. Va. Sept. 29, 2014) (quoting *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006)); *Tyree*, 2014 WL 5320566, at *4. The Fourth Circuit has explained that the "role of the district court . . . is to distinguish opinion testimony that embraces an ultimate issue of fact from opinion testimony that states a legal conclusion." *United States v. Barile*, 286 F.3d 749, 760 (4th Cir. 2002). "The best way to determine whether opinion testimony contains legal conclusions, 'is to determine whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular.'" *Id.* (quoting *Torres v. Cty. of Oakland*, 758 F.2d 147, 151 (6th Cir. 1985)).

The Court has further consistently excluded expert opinions regarding legal conclusions drawn from the facts. Bard Wave 4-5 Order at 3. The Bard Wave 4-5 Order excluded Dr. Rosenzweig's repeated statements that the defendant "failed to act as a reasonable and prudent medical device manufacturer," holding that these statements "drew legal conclusions from the facts" and are inadmissible because whether the defendant acted as a reasonable and prudent medical device manufacturer "is a question for the jury." (Bard Wave 4-5 Order at 3; *see also Lewis* Opinion at 35 (*citing United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006))). The *Huskey*, *Edwards*, and *Tyree* Opinions state, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." (*Huskey* Opinion at 6; *Edwards* Opinion at 6; Tyree Opinion at 8).

Clearly, the Court's prior exclusion of Dr. Rosenzweig's legal opinions has not deterred him from offering essentially the same opinions here. Various sections of his Report conclude

with the same legal opinion that, as a result of his preceding analysis, "Bard failed to act as a reasonable and prudent medical device manufacturer by manufacturing and selling its mesh in a permanent prosthetic implant like Align." (*See* Report § III.A.2 at 26, § III.A.3 at 28, § III.A.5 at 37, § III.A.6 at 40, § III.A.7 at 43, § III.D at 60, § III.E at 61, Conclusion at 65). Dr. Rosenzweig also offers other legal opinions, including that Bard "has clearly failed to adequately warn physicians about the nature and the significance of adverse events and risks associated with the Align," that Bard's IFU "is, and has always been, inadequate and defective," and that Bard "deviated from the standard of care required of a reasonable medical device manufacturer by failing to adequately disclose these known adverse reactions and risks to physicians." (*Id.* § III.C.1 at 56-57; *see also id.* § III.C.2 at 58-59; *see also* Rosenzweig Dep. I at 103:15-104:24). These are quintessentially legal opinions drawn from the facts, and must be left to the jury. All of Dr. Rosenzweig's legal opinions should therefore be excluded.

IV. DR. ROSENZWEIG CANNOT OFFER OPINIONS REGARDING THE PURPORTED INSUFFICIENCY OF BARD'S TESTING.

This Court has consistently excluded opinions relating to product testing that lack a scientific and/or regulatory foundation and amount only to the "personal opinion" of a witness without industry experience applying actual standards for the design and testing of medical devices. *Sanchez*, 2014 WL 4851989, at *31 (excluding Dr. Slack's "unsupported personal opinion"); *Lewis*, 2014 WL 186872, at *18-19 (excluding Dr. Pence's testing opinions as lacking a "reliable methodology 'reliably applied . . . to the facts of the case'" (citation omitted)); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at, 612 (excluding Dr. Shull's testimony on design, testing and materials based only on personal experiences and observations and internal Bard documents); *id.* at 631 (excluding Dr. Kessler's "personal opinions" regarding need to conduct human clinical trials); *Huskey*, 2014 WL 3362264, at *12 (excluding Dr. Pandit's testing opinions because "he

cites no scientific support for these opinions"). Absent "authority" supporting design and testing opinions that supports and explains why Bard was "required" to do something different, plaintiffs' experts should not be permitted to offer mere personal opinions on these subjects. *Sanchez*, 2014 WL 4851989, at *31; *see also In re Diet Drugs*, MDL No. 1203, 2001 WL 454586, at *18 (E.D. Pa. Feb. 1, 2001) (excluding a purported regulatory opinion from former FDA official as "a personal opinion about what standards he believes should apply to pharmaceutical company conduct").

On numerous prior occasions, this Court has noted Dr. Rosenzweig's lack of qualifications to testify regarding testing of mesh devices, and has excluded him from testifying regarding the alleged insufficiency of the defendant's product testing. (*E.g.*, BCS Order at 2; *Huskey* Opinion at 9; *Edwards* Opinion at 15). In each case, Dr. Rosenzweig stated in his expert report and/or at deposition that the defendant failed to undertake testing "to determine whether the marked cytotoxicity found in the TVT mesh had long term consequences for permanent human use." (*Huskey* Opinion at 9; *Edwards* Opinion at 15). The Court found, however, that Dr. Rosenzweig "is not qualified to opine that [defendant's] testing was insufficient," because there was "no indication" that he "has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake." (*Huskey* Opinion at 10; *Edwards* Opinion at 17). The Court therefore excluded Dr. Rosenzweig's opinions concerning the sufficiency of the defendant's testing. (*Id*.).

The *Huskey* and *Edwards* Opinions also excluded Dr. Rosenzweig from testifying regarding the defendant's supposed failure to provide adequate training. In each case, Dr. Rosenzweig opined that the defendant "failed to provide adequate training" to physicians regarding the use of the subject device. (*Huskey* Opinion at 11-12; *Edwards* Opinion at 18). The

Court found that this opinion was defective because it was based on a "narrative review of corporate documents," and also because "it is unreliable because Dr. Rosenzweig fails to describe the basis for his opinion that [defendant's] training was inadequate." (*Id.*).

The exclusion of Dr. Rosenzweig's opinions regarding the appropriate testing or training a medical device manufacturer should undertake, based on his lack of experience or knowledge in this area and his failure to provide a basis for his opinions, is appropriate and necessary. Federal Rule of Evidence 702 requires a witness to be "qualified as an expert by knowledge, skill, experience, training, or education." Rule 702(a) further requires that the expert's "scientific, technical, or other specialized knowledge" must "help the trier of fact to understand the evidence or to determine a fact in issue." And Rule 702(b) through (d) require expert testimony to be "based on sufficient facts or data," require the testimony to be "the product of reliable principles and methods," and require the expert to reliably apply "the principles and methods to the facts of the case."

Consistent with these requirements, the Court has excluded expert opinions which exceed the scope of the expert's knowledge, skill, experience, training, or education, and which fall outside of the expert's scientific, technical, or other specialized knowledge. For example, the Court previously excluded the conclusory opinions of plaintiffs' expert urogynecologist regarding Bard's product warnings, finding that the expert had failed to "provide a reliable basis for his opinions of what Bard should have done," a deficiency the Court attributed to his "lack of expertise in the specific area of warnings and labels for medical devices." *In re: C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013). Similarly, in these cases, Dr. Rosenzweig's lack of expertise in the area of medical device testing precludes his qualification as an expert in that

area, and prevents his (non-existent) scientific, technical, or other specialized knowledge in the field from helping the jury.

Here, as in the past, Dr. Rosenzweig offers opinions regarding the supposed inadequacy of Bard's testing or failure to test, with no indication of the knowledge, skill, experience, training, or education that would qualify him to opine regarding the appropriate testing a medical device manufacturer should undertake. For example, after giving his inadmissible opinion of what Bard "knew" regarding the alleged dangers of polypropylene, as well as a lengthy narrative regarding internal Bard emails, Dr. Rosenzweig opines:

> Given the information available to Bard concerning the dangers of polypropylene coupled with the explicit warning and other contents of the MSDS, at a minimum, ***Bard should have conducted clinically relevant testing*** to determine if naturally occurring conditions in the vagina could cause polypropylene used in Align to alter inside the woman's body (as well as other complications), and if so, what materials are released into the body as a result, and what impact would those materials have on the body. * * *
>
> C.R. Bard, Inc. did not undertake any long term testing to determine whether or not these warnings on the polypropylene resin manufacturers MSDS were associated with long term consequences for permanent human use.

(Report § III.A.1 at 17 (emphasis added)). He later reiterates the same opinion with regard to "clinically relevant testing" Bard "should have conducted" regarding mesh degradation, describing it as his opinion "to a reasonable degree of medical certainty." (*Id*. § III.A.2 at 24). The Report and Dr. Rosenzweig's testimony contain similar opinions regarding the alleged inadequacies of Bard's testing. (*See, e.g.,* Report § III.A.5 at 37, § III.A.7 at 42-43, § III.B at 46, § III.B at 48, § III.E at 60-61; Rosenzweig Dep. I at 184:20-186:18, 190:12-193:7, 295:17-24).

Dr. Rosenzweig does not identify what knowledge, skill, experience, training, or education qualifies him to opine regarding the adequacy or inadequacy of Bard's testing. In addition, he does not describe what "clinically relevant testing" he believes should have been conducted, nor does he offer any reliable basis for his opinion that such testing should have been

conducted. Thus, like the inadequate testing and training opinions this Court excluded in prior cases, Dr. Rosenzweig's testing opinions here lack any reliable basis or explanation. These opinions are unqualified, unexplained, and unsubstantiated, and should therefore be excluded.

V. DR. ROSENZWEIG CANNOT OFFER OPINIONS REGARDING THE ALLEGED INADEQUACY OF THE BARD PATIENT BROCHURES

Similar to Dr. Rosenzweig's opinions regarding Bard's alleged inadequate testing, the Report also offers opinions regarding the sufficiency of the Bard Patient Brochures that are unqualified and lack any reliable basis. Dr. Rosenzweig opines, with citation to an FDA guidance document, that a patient brochure is "considered patient labeling" and "should include the risks and benefits associated with the device in a manner that is meaningful to the user," which "should be conveyed in an effective and meaningful way to the use [sic] in deciding whether to use a device, or undergo a procedure that uses the device." (Report § III.C.2 at 57). He then opines that the Bard Patient Brochures could "easily" have ensured patients received a copy of the product IFU by including "the IFU or at least the Adverse Events section of the IFU within the patient brochure itself," but "chose not to do so," and thereby "deprived patients of an opportunity to fairly evaluate the risks and benefits of the device from a review of the patient labeling, as required by the FDA guidance documents." (*Id.* § III.C.2 at 58). Dr. Rosenzweig concludes that the Bard Patient Brochure "is, and has always been, inadequate and defective." (*Id.*). Later, Dr. Rosenzweig offers additional opinions that the Bard Patient Brochures are "misleading," gives women a "false impression" regarding success rates, performance, complications, surgery, and recovery time, and "misleads the patient" regarding complications, risks, and recurrence of symptoms. (*Id.* § III.F at 61-64).

Like Dr. Rosenzweig's opinions on Bard's allegedly defective testing, Dr. Rosenzweig does not indicate any basis in his knowledge, skill, experience, training, or education to opine on

the adequacy or inadequacy of a patient brochure, much less to opine on whether it meets the standards of the FDA's guidance documents for "patient labeling." He also provides no reliable basis for his conclusion that the warnings contained in the Bard Patient Brochures were inadequate. Accordingly, his opinions regarding the Bard Patient Brochures, like those regarding Bard's medical device testing, should be excluded as unqualified and lacking a reliable basis.

CONCLUSION

For all the foregoing reasons, Bard respectfully requests that the Court exclude or limit certain opinions of Dr. Rosenzweig as set forth above.

Dated: August 15, 2019

Respectfully submitted,

GREENBERG TRAURIG, LLP

/s/ *Lori G. Cohen*

Lori G. Cohen
Terminus 200
3333 Piedmont Road, N.E., Suite 2500
Atlanta, Georgia 30305
(678) 553-2100
(678) 553-2212 (facsimile)
CohenL@gtlaw.com

Michael K. Brown
REED SMITH LLP
355 South Grand Avenue, Suite 2900
Los Angeles, California 90071-1514
(213) 457-8000
mkbrown@reedsmith.com

Attorneys for Defendant C. R. Bard, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on August 15, 2019, I caused the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ *Lori G. Cohen*
Lori G. Cohen
GREENBERG TRAURIG, LLP

Attorney for Defendant C. R. Bard, Inc.